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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. William James Heaney
President
Electronic Waveform Laboratories, Incorporated
16168 Beach Boulevard, Suite 232
Huntington Beach, California 92647

Re: H-Wave Powered Muscle Stimulator, K915230; EWL P-TENS for General Dentistry, K873604

Dear Mr. Heaney:

The Food and Drug Administration (FDA) has reviewed promotional materials for the H-Wave Powered Muscle Stimulator (H-Wave) and for the EWL P-TENS H-Wave for general dentistry. The H-Wave and EWL P-TENS are manufactured by Electronic Waveform Laboratories, Incorporated (EWL) and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The H-Wave muscle stimulator has been cleared under section 510(k) of the Act and is intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. Additionally, muscle stimulators may make the following additional claims: (1) relaxation of muscle spasm; (2) prevention or retardation of disuse atrophy; (3) increasing local blood circulation; (4) muscle re-education; (5) immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and, (6) maintaining or increasing range of motion. The EWL P-TENS for general dentistry is intended to provide dental anesthesia during amalgam, composite, and crown preparations.

We have reviewed promotional materials for the H-Wave Powered Muscle Stimulator and for the EWL P-TENS devices which were received by our Los Angeles District Office. These materials from a distributor, and information on your home page at the Internet address: http://www.h-wave.com, indicate that EWL is promoting the H-Wave and EWL P-TENS devices for intended uses that have not been cleared by the Agency.

Examples of these claims for the H-Wave include:

-HIV/Aids (peripheral neuropathy)
-arthritis
-reflex sympathetic dystrophy (RSD)
-diabetic neuropathy

-herniated nucleus pulposus
-lymphedema
-migraine headache
-avascular necrosis
-reduction of acute and chronic edema
-wound healing claims (accelerated tissue repair, cellulitis, decubitis ulcers)
-osteoporosis
-prevention of adhesions/scar tissue
-failed back surgeries
-sciatica
-vascular insufficiency
-bells palsy
-facial nerve disorder
-peripheral vascular disease.

Additional claims found on your home page for the EWL P-TENS device for dental applications which have not been cleared by the Agency include: scaling (sub-gingival), root planing, and curettage.

Promotional claims for a given device are limited to the indications for use that were cleared as part of the 510(k) premarket notification submission. The six intended uses for muscle stimulators listed above (relaxation of muscle spasms...), and the intended uses identified for general dentistry (anesthesia for amalgams, crowns, composites) are the only intended uses cleared for the H-Wave and EWL P-TENS devices, respectively. Manufacturers may not narrow the intended use of a device to a specific body site, tissue, specific patient population, or disease state without the submission and prior clearance of a new 510(k) premarket notification.

The H-Wave and EWL P-TENS devices are adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a), or approved applications for investigational device exemptions (IDE's) under section 520(g).

The H-Wave and EWL P-TENS are also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use(s) of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

Additionally, we note that your promotional materials make reference to the FDA name, registration, 510(k) numbers, and FDA clearance. Examples are: "H-Wave is registered with the US Food and Drug Administration for safety and efficacy. The FDA has issued 510(k) numbers to H-Wave for the following applications..." Reference to FDA, in advertisements or other promotional materials for medical devices is prohibited by the Act and represents misbranding under section 502(a). The reference for this may be found under 21 CFR 807.39 and 807.97, "Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding," and, "any representation that creates an impression of official approval because of complying with the premarket notification regulations is misleading and constitutes misbranding." Electronic

Waveform Laboratories may not make any reference to FDA clearance/approval, use of 510(k) numbers and/or reference registration and listing of your devices. These references in your promotional materials should therefore cease immediately.

This letter is not intended to be an all-inclusive list of deficiencies associated with your H-Wave and EWL P-TENS devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. The Agency is concerned that EWL, by its promotions, has made a direct connection between the name "H-Wave" and these serious off-label conditions. EWL's proposal should address how the name "H-Wave" can remain in the marketplace without continuing to imply that it is effective in treating the above conditions and/or disease states. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Los Angeles District Office, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely yours,

Byron Tart for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health